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Supreme Court, U.S.
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No. 90-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ANNE ELISABETH KOLLER,

Petitioner,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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February 5, 1991

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QUESTIONS PRESENTED

1. Under Fed. R. Evid. 703, may federal courts exclude the testimony of concededly qualified expert witnesses solely on the finding that, given the weight of opposing expert testimony, the factual *conclusions* reached by the experts are incorrect and hence not "reasonable"?

2. Under the Federal Rules of Evidence, may the courts of appeals promulgate specialized, common-law evidence rules establishing "as a matter of law" the incorrectness, and hence inadmissibility, of particular conclusions about ultimate scientific facts?

3. Consistent with the Constitution, may the lower federal courts pursue efficiency in "mass tort" or other litigation by using a single case to pronounce binding conclusions of ultimate scientific fact on a key issue common to a category of cases — and thereafter bar all other litigants from trying that issue, even though they were not parties to, or represented in, the first case?

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OPINIONS BELOW

The *per curiam* order of the United States Court of Appeals for the District of Columbia Circuit granting summary affirmance is unreported and reprinted as Appendix A, at page A1.[1] The memorandum opinion of the United States District Court for the District of Columbia, granting judgment in favor of respondent and dismissing the complaint, is unreported and reprinted as Appendix B, at page A3.

JURISDICTION

The *per curiam* order of the Court of Appeals was announced on August 31, 1990. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on November 7, 1990. See Appendix C, at page A11. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

The Federal Rules of Evidence were enacted by Congress as a statute in 1975, Pub. L. No. 93-595, 88 Stat. 1926 (1975), 28 U.S.C. app. (1988). Rule 402 provides:

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

> All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States,

[1] References to the appendices bound with this Petition are styled "A__". References to the four-volume Appellant's Appendix filed below in the Court of Appeals will be styled "C.A. App. __".

by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 104(a) of the Federal Rules of Evidence provides:

> **Rule 104. Preliminary Questions**
>
> **(a) Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Rule 702 of the Federal Rules of Evidence provides:

> **Rule 702. Testimony by Experts**
>
> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703 of the Federal Rules of Evidence provides:

> **Rule 703. Bases of Opinion Testimony by Experts**
>
> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The Fifth Amendment to the United States Constitution provides in relevant part:

> No person shall . . . be deprived of life, liberty, or property, without due process of law . . . .

The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

1. Summary

This case is one of many filed in the federal courts under diversity jurisdiction alleging birth defects from the anti-nausea drug Bendectin. It presents important and recurring issues, on which the circuits are in conflict, concerning the proper interpretation of the expert testimony rules enacted by Congress in the 1975 Federal Rules of Evidence, particularly Rule 703. This case also involves the constitutional issues raised by the current debate among the federal courts of appeals concerning attempts to reduce the burden of "mass tort" litigation by employing evidentiary rulings in *one* case to resolve disagreements among qualified experts, issuing a *general* pronouncement about scientific truth on a key issue, and then requiring that this pronouncement bind all future litigants even if they are thereby denied *their own* day in court on that key issue and its application to their case.

In the expert testimony rules that Congress enacted in order to greatly *expand* the range of expert opinion available to juries in federal trials, the D.C. Circuit below, as well as the First Circuit in an earlier case, have purported to find a device that supposedly *grants judges the power to try the entire case at the threshold level of admissibility*. Under Rule 703, these circuits have held, *all* of a party's expert opinion testimony on an issue may be excluded if the court decides that the ultimate *conclusion* of the experts is not "reasonable," because of the greater weight of the opposing experts' testimony. *See* pp. 11-15, *infra*. Several other circuits have, to a lesser extent, used Rule 703 to second-guess the persuasiveness of expert testimony. *See* pp. 24-25, *infra*. Solely under Rule 703, the court below required exclusion of the testimony of *all sixteen* experts who testified in support of the conclusion that Bendectin causes birth defects, including those who specifically stated that it caused petitioner's injuries. This tactic flouts Congress's clear language and intent in enacting Rule 703, under which the persuasiveness of an expert's conclusions is irrelevant — as several other circuits have held and as the Third Circuit has recently reiterated in another Bendectin case, expressly rejecting the contrary Bendectin decisions of the D.C. and First Circuits. (Part I, *infra*.) This Court should resolve the longstanding and important circuit conflict over the meaning of Rule 703, and in doing so overturn the extreme use of Rule 703 pioneered by the First and D.C. Circuits.

Moreover, in holding that certain conclusions reached by experts are incorrect and, therefore, "*as a matter of law*" are inadmissible in all future cases, the court below has engaged in exactly the type of traditional, circuit-by-circuit, common-law evidence rulemaking that the Federal Rules of Evidence — by requiring *uniform* rules for all classes of cases throughout the Nation — were passed to prevent. The Rules displace the power of lower federal courts to promulgate special evidentiary

rulings, as the court below has done with respect to Bendectin litigation. (Part II, *infra*). This Court should use this case to enforce Congress's basic policy choice and put an end to such impermissible aggrandizement of federal judicial power.

The ruling of the court below also presents grave constitutional issues that are increasingly confronting the lower federal courts as they work to resolve "mass tort" cases efficiently. The theory that federal judges can use the Federal Rules of Evidence to cut off jury trials on contested issues of fact, by nakedly weighing conflicting testimony in deciding which evidence to *admit*, violates the Seventh Amendment, which was passed in order to prevent such abuses by an autocratic Judiciary and thereby to help legitimate the Article III courts. For a court to attempt to put an end to "duplicative" litigation over similar issues by binding a litigant to a judgment about *ultimate scientific fact* reached in another case, to which he or she was not a party or privy, completely denies well-established rights to procedural due process. The separation-of-powers and federalism problems with Article III judges using individual cases to issue scientific edicts designed to end dispute over state-law issues are equally severe. (Part III, *infra*).

2. Factual Background

The issues presented on this petition concern not whether Bendectin causes birth defects in general, or whether it caused petitioner's particular birth defects, but rather how such scientific issues must be decided under the Federal Rules of Evidence and under the Constitution. For that reason it is not necessary to itemize the specific content of the scientific testimony in this case. An understanding of the questions presented for review does, however, require a sketch of the types of evidence that exist regarding Bendectin, and the differences in the methods of scientific investigation involved.

Bendectin was developed by respondent Richardson-Merrell, Inc. ("Merrell")[2] as an anti-nausea drug to be taken by pregnant women to combat morning sickness in early pregnancy. In 1956 the FDA permitted Bendectin to be placed on the market. At the time of initial marketing, neither Merrell nor the FDA had conducted any studies to determine the effect of the drug on the human fetus — a result of the prevailing scientific belief that the womb was a safehouse against environmental dangers. Although the embryos of amphibians, fish, and chicks had been shown "to be quite susceptible to unfavorable influences during development," these tests "were not generally accepted as purporting similar vulnerability for higher animals." J. Wilson, "Current Status of Teratology," in 1 *Handbook of Teratology* 47 (ed J. Wilson and F. Fraser 1977) (reprinted at C.A. App. Tab 27). Instead, "[i]t was widely assumed in biology and in medicine that the mammalian embryo developed within the virtually impervious shelter of the uterus and the maternal body where it was protected from extrinsic factors." *Ibid.*

Conventional scientific wisdom, of course, proved quite wrong several years later, with "the appearance of an epidemic of limb-reduction malformations" in babies whose mothers had taken the "presumably harmless sedative-hypnotic drug thalidomide," which made clear the vulnerability of human embryos "to certain environmental agents even though these have negligible or no toxic effects in postnatal individuals." *Id.* at 48. The thalidomide tragedy spurred the rapid development of the scientific field of "teratology" — the study of "teratogens," or substances that produce malformations in human fetuses. *Id.* at 48-49.

Teratology quickly became a major area of study in the pharmacology departments at virtually all universities, borrowing

[2] The company is now succeeded in interest by Merrell Dow Pharmaceuticals, Inc.

investigative techniques from the field of toxicology, which concerns itself with the effects of substances on living cells. As a widely prescribed drug, Bendectin fell under close scrutiny. Before the drug was removed from the market in 1983, doctors had filed thousands of reports with the FDA or Merrell noting deformed children born of Bendectin mothers. In light of such concerns, teratologists labored for over a decade, examining all feasible sources of information to determine whether Bendectin causes birth defects. Pharmacology data revealed that Bendectin's antihistaminic component (doxylamine succinate) crosses the placental barrier and therefore can cause defects to the fetus. As to *direct* evidence of causation, because experimentation on human fetuses is of course legally and ethically impermissible, teratologists relied on the standard substitute: controlled experimentation on animals. Breakthroughs in *in vitro* studies, involving microscopic examination of animal cells subjected to Bendectin while in the process of cell division, indicated that Bendectin could trigger abnormal cell development associated with birth defects. *In vivo* studies subjecting various animal species to dosages of Bendectin during fetal formation provided further evidence of teratogenicity.

As to *indirect*, circumstantial evidence of causation, researchers in the field of epidemiology began collecting human data through epidemiological studies comparing groups of women who had taken Bendectin during pregnancy with groups who had not, and reporting the incidence of birth defects in each group in an attempt to determine a correlation. The data from these studies usually indicated a substantially higher rate of birth defects among women taking Bendectin — although not as high a rate of defects as had occurred with thalidomide.

To be sure, in any one such epidemiological study taken alone, there was always the danger that the observed differences in the rate of deformities among Bendectin and non-Bendectin

mothers might be the result of chance, given the relatively small number of mothers in each study and difficulties in measuring exact levels of Bendectin usage and in controlling for other possible sources of birth defects. For this reason, scientists in the field of *epidemiology* have traditionally been unwilling to conclude that a *single* study constitutes evidence of causation unless it meets a strict test of "statistical significance" — i.e., when statistically they can be at least *95% confident* that an observed correlation is not due to chance. If the level of certainty falls even slightly short of this strict standard, the study will typically be reported as concluding that there is no indication of causation. *See DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-49 (3d Cir. 1990). Thus epidemiologists might conduct a string of studies on Bendectin, *each one* indicating a *90% confidence* that Bendectin causes birth defects, and scientists in the field of epidemiology would report that there is *no "statistically significant" evidence of causation*.

Scientists in the field of *teratology*, however, routinely consider multiple sources of information in investigating whether substances cause birth defects. They assess epidemiological data in light of other data from direct experiments and thus place less reliance on the certainty demanded by "statistical significance" testing. By examining the data *as a whole*, including the actual observations made in *multiple* epidemiological studies, they reduce the danger of error from considering a single epidemiological study in isolation, so that continued use of "statistical significance" standards becomes arbitrary and unhelpful. *See, e.g., DeLuca, supra*, 911 F.2d at 947-49.

Based on these sources of data taken together, by the late 1970s a substantial number of eminent scientists in the field of teratology and related fields had reached the scientific conclusion that Bendectin is a potent teratogen capable of causing a wide variety of birth defects. As a result large numbers of lawsuits were filed alleging birth defects resulting from use of Bendectin.

To be sure, no consensus existed (or exists today) on the issue. Merrell found support among significant numbers of experts who questioned the strength of the various sources of evidence of causation. Merrell relied most heavily on specialists in the field of epidemiology, who argued that epidemiological studies, because they involve observations of humans and not animals, constituted the best evidence of causation. These experts observed that such studies on Bendectin had failed to show a causal link to most types of birth defects at a "statistically significant" 95% confidence level. Using this filter of "statistical significance" drawn from the field of epidemiology, then, Merrell argued that it was simply not possible to demonstrate that Bendectin is a teratogen — even though the underlying epidemiological studies, taken as a whole, generally revealed increased levels of birth defects in children of mothers who had taken Bendectin during pregnancy.

In September 1980, Merrell garnered some governmental support for the view that there was not yet sufficient proof that Bendectin was a teratogen. An FDA advisory committee convened largely at the behest of Merrell examined the available evidence in a two-day conference and endorsed this general outlook, "conclud[ing] that the relevant information 'did not demonstrate an increased risk of birth defects with Bendectin use,' but urg[ing] that studies be continued." *DeLuca, supra,* 911 F.2d at 943 (quoting committee conclusions).

3. Initial Procedural History of Case and Summary Judgment Denials

Petitioner was born on June 9. 1979, with grievous, multiple "limb reduction" birth defects. Her left leg is shortened, with minimal hip movement, a fixed knee, only one lower leg bone, and a deformed foot. Her right leg consists of a one-centimeter appendage. Her left arm consists of a short bone segment which tapers to a point. She has no right arm at all. Suit was instituted

on her behalf in 1980 on a variety of tort and contract grounds, alleging that her mother took Bendectin during the critical period when her limbs were forming, and that the Bendectin had caused her birth defects.

After discovery, in 1982 Merrell brought a motion for summary judgment on the issue of causation, filing elaborate and lengthy papers arguing that petitioner's case rested on "speculative evidence and opinions" that were not capable of proving causation. The District Court denied the motion, finding that a genuine issue of material fact existed. *See* Appendix D, at A13-A15. The District Court pointedly noted that the theory advanced for summary judgment "would effectively deprive any plaintiff of reaching the jury where the product at issue was not an accepted cause of birth defects or other diseases." A15.

Following unrelated proceedings on a procedural issue in the Court of Appeals and this Court during which the litigation was stayed,[3] Merrell renewed its motion for summary judgment, arguing again that no jury issue on causation was presented, citing recent cases in other jurisdictions where the jury had returned verdicts for the defense,[4] and relying heavily on

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[3] *See Koller* v. *Richardson-Merrell, Inc.*, 737 F.2d 1038 (D.C. Cir. 1984) (ruling in interlocutory appeal that District Court's order disqualifying plaintiff's counsel was invalid), *vacated and remanded*, 472 U.S. 424 (1985) (holding that such orders are not collateral orders subject to immediate appeal under 28 U.S.C. § 1291).

[4] Merrell prominently cited the multi-district common issues trial involving over 800 cases, *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989), in which the jury happened to decide that Bendectin does not cause birth defects — but in which Judge Rubin pointedly noted that "[b]oth sides presented testimony of eminently qualified and highly credible experts who differed in regard to the safety of Bendectin" and that the jury was confronted with "assess[ing] the credibility of each witness [to] resolve all conflicts of fact." *Id.* at 1244 (emphasis added). The Sixth Circuit agreed that "that the jury verdict following trial here might have been for the plaintiffs instead of for the defendant." 857 F.2d at 325.

this Court's "*Celotex* trilogy" liberalizing summary judgment practice. In 1986 the District Court reaffirmed its earlier ruling, finding "that there exists a genuine issue of material fact as to whether Bendectin caused Anne Koller's birth defects." Appendix F, at A20.

Petitioner concurrently brought a motion for partial summary judgment on causation arguing that Merrell should be collaterally estopped from denying that Bendectin *generally* is capable of causing birth defects, citing among other cases *Oxendine* v. *Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986), *cert. denied*, 110 S.Ct. 1121 (1990), in which the D.C. Court of Appeals had upheld a $750,000 verdict against Merrell on far less evidence that proffered by petitioner.[5] Despite Merrell's prior day in court, the District Court held that "there is no basis in law to collaterally estop defendant from litigating the issue of causation in this action." Appendix E, at A19.

4. The *Richardson* and *Ealy* Decisions

Before trial, this case was stayed pending a decision by the Court of Appeals below in another case alleging harms from Bendectin, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989), in which the Court of Appeals interpreted Fed. R. Evid. 703 as permitting a court to weigh the persuasiveness of the *conclusions* of competing expert witnesses, and exclude one side's

[5] In *Oxendine*, in which the plaintiff presented only one main witness and one rebuttal witness on causation, the trial court had granted judgment n.o.v. for Merrell after examining each item of evidence taken *alone* and finding insufficient evidence of causation. 506 A.2d at 1110. The D.C. Court of Appeals ruled that under the substantive law of the District, the trial court had erred "in failing to consider the [main] expert's testimony that all of the studies, *taken in combination*, did support" a finding of causation on the part of the jury. *Ibid.* (emphasis in original). It noted that in reviewing the nature of the evidence on a judgment n.o.v., "the court must view the evidence as a whole, not in fragments," because "[l]ike the pieces of a mosaic, the individual studies showed little or nothing when viewed separately from one another, but they combined to produce a whole that was greater than the sum of its parts." *Ibid.*

entire expert testimony on the ground that the conclusions are not "reasonable". The *Richardson* Court surveyed the current state of Bendectin evidence and ruled that unless new types of evidence emerge, expert opinion that Bendectin causes birth defects must be excluded because it is against the supposedly overwhelming weight of Merrell's epidemiological evidence to the contrary. *Richardson*, and the Court of Appeals' confirmatory opinion in *Ealy* v. *Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990), were the sole basis for the Court of Appeals' summary disposition of this case below — rendering the earlier summary judgment motions irrelevant and denying petitioner a trial on the key scientific issues she raised. *See* Appendix A, at A1.

The *Richardson* trial court considered causation evidence from several plaintiffs' experts focusing on the standard four types of data relied on in the field of teratology and related fields: chemical structure analysis, and *in vitro*, *in vivo* and epidemiological data. Experts basing their conclusions on such data were opposed primarily by Merrell's epidemiological experts, who argued chiefly that the raft of studies to date had not demonstrated a "statistically significant" association between Bendectin and birth defects, and therefore it was impossible to prove causation. *Id.* at 826-27. After a jury verdict finding causation, the trial court sided with Merrell's experts and granted judgment n.o.v. on the conclusion that "no reasonable jury could find that [the plaintiff's] birth defects were more likely than not caused by Bendectin." *Id.* at 825.

The Court of Appeals affirmed the trial court on the theory that Rule 703 of the Federal Rules of Evidence required exclusion of all of plaintiffs' expert testimony.[6] Following the hold-

[6] In doing so the Court of Appeals sought to avoid potential problems under *Erie R.R.* v. *Tompkins*, 304 U.S. 64 (1938). As the plaintiffs had argued on appeal, and as the *Richardson* court acknowledged, *see* 857 F.2d at 825 n.9, the trial court's judgment n.o.v. was in tension with the recent *Oxendine*

ing of the First Circuit in *Lynch* v. *Merrell-National Laboratories Division of Richardson-Merrell, Inc.*, 830 F.2d 1190 (1st Cir. 1987), *aff'g*, 646 F. Supp. 856 (D. Mass. 1986), which affirmed a grant of summary judgment on causation based on Rule 703, the *Richardson* panel determined "that the epidemiological studies on Bendectin conclude[ ] overwhelmingly that the drug does not cause birth defects." 857 F.2d at 831.

In the *Richardson* trial, plaintiffs' experts had testified at trial without contradiction, in evident fulfillment of Rule 703, that experts in the field of teratology and related fields routinely and reasonably rely on all four types of data in drawing inferences about whether substances cause birth defects. Yet the *Richardson* panel opined, without analyzing the language or legislative history of Rule 703, that in making a Rule 703 determination, a court must "look behind [an expert's] ultimate conclusion . . . and analyze the adequacy of its foundation." *Id.* at 829.

The court explained that this involves not an assessment of whether experts rely on certain types of information in practice and whether it is generally reasonable to do so — irrespective of the conclusion ultimately arrived at — but rather an assessment of the court's view of the *weight of the opinion* derived from this information, compared with the weight of contrary opinion on the other side. The *Richardson* court's theory was that the existence of numerous epidemiological studies, individually failing to conclude with *95% confidence* that Bendectin causes birth defects, *id.* at 831, somehow negates the other

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case, *see supra* note 5, holding that under the substantive law of the District of Columbia the four types of evidence relied on by plaintiffs' experts could easily support a jury finding of causation. The Court of Appeals stated that "*Erie* does not affect the federal courts' application of the Federal Rules of Evidence," *ibid.*, and concluded that inasmuch as the question of adequate basis under Rule 703 was an "issue[ ] of law falling within the province of the court," the function of the jury was not being usurped. *Id.* at 833.

probative information relied on by the plaintiffs' experts, and therefore the foundation could not be adequate. *Id.* at 830, 832.

In *Ealy*, a year and a half later a separate panel of the D.C. Circuit confirmed and cemented the *Richardson* holding, announcing that, on the basis of current scientific knowledge, all future Bendectin litigation in the Circuit will be barred, because *as a matter of law* no expert opinion finding causation is even admissible in evidence.

Ealy involved Merrell's appeal from a trial judge's *refusal* to set aside a jury verdict in favor of the plaintiffs. Merrell argued "that the *Richardson* decision provides a binding legal precedent that requires reversal of the trial court's denial of its motion for judgment n.o.v." 897 F.2d at 1161. The plaintiffs responded that an evidentiary ruling in a separate case to which they were not a party or privy could not possibly apply to them, that they were entitled to have evidence admissibility issues evaluated on the record in *their* case alone, and that, in admitting their expert opinion evidence, the trial judge had agreed with the uncontradicted testimony of their experts that the types of data being relied on are typically and reasonably relied upon in the field of teratology and related fields.

The *Ealy* court nonetheless announced that *Richardson* would henceforth be treated as articulating a "binding legal rule," applicable to *all* cases, because "an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of 'a wealth of published epidemiological data' to the contrary." *Id.* at 1160 (citing *Richardson*, 857 F.2d at 832). The *Ealy* court further elaborated:

> The *Richardson* court concluded, as a matter of law, that the "wealth of published epidemiological data . . . none of which has concluded that the drug is teratogenic . . . must be given their just due." 857

> F.2d at 832. Therefore, under Rule 703, an opinion refuting this scientific consensus is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base this opinion. It is this uncontroversial rule of evidence that is the *ratio decidendi* of *Richardson* and this case.

897 F.2d at 1162.[7]

In sum, the *Ealy* court ruled that the large number of *published, peer-reviewed* epidemiological studies all *failing* to indicate with 95% confidence that Bendectin causes birth defects "must be recognized as the measuring stick for the admissibility of expert testimony on this issue," that this makes the conclusions of plaintiffs' experts not "reasonable" and hence inadmissible under Rule 703, and that only if stronger "new epidemiological or other types of data" are generated by scientific research may Bendectin plaintiffs litigate their claims. *Id.* at 1163-64. As *Ealy* makes clear, the D.C. Circuit's interpretation of Rule 703 permits it to force the exclusion of evidence in any type of case where a panel believes that expert opinions reaching one set of conclusions are sufficiently outweighed by expert opinions on the other side.

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[7] The *Ealy* court further observed: "Because *Richardson* provides a binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects, the Ealys can only avoid that decision by showing that the record here is materially different from *Richardson*." 897 F.2d at 1162. The court found no such difference, given that *most* of the studies relied on by the Ealys' experts were "virtually the same" as *Richardson* and that the *new* data presented had "dubious significance in the face of the epidemiological data." *Id.* at 1162-63.

The *Ealy* court again turned aside the *Erie* objection, *see supra* note 6, explaining that "this case, like *Richardson*, turns on the admissibility of the expert opinion testimony," and that it was "enforcing a procedural rule governing admissibility" and "not supplanting substantive state rules on the sufficiency of evidence." *Id.* at 1163.

5. The District Court's Decision Below

After *Richardson* was decided, but before *Ealy* was handed down, on Merrell's motion the District Court below ordered petitioner to show cause why the case should proceed, and specifically asked petitioner to identify expert opinion testimony that would meet the strictures announced in *Richardson*. In response petitioner exhaustively detailed the proposed testimony of her sixteen expert witnesses in support of causation, and chronicled the large number of cases where such testimony had been accepted nationwide in federal courts as creating a jury issue; argued that *Richardson* could not be squared with the Federal Rules of Evidence; and argued that the *Richardson* holding could not be binding on petitioner and that she had a right to her own day in court.

In its memorandum opinion the District Court reviewed the *Richardson* holding and concluded that the Court of Appeals had "found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, *in vivo, in vitro* studies, or reformulated epidemiological data, is not admissible," and that therefore "the issue of causation shall not be presented to a jury unless the plaintiffs offer scientific evidence other than that which has heretofore been proffered." (A8-A9). Thus, despite its earlier two rulings upholding petitioner's right to present her case to a jury, the District Court was constrained by the *Richardson* rule within the D.C. Circuit to grant judgment in favor of the defendant. (A9).

6. The Court of Appeals' Decision Below

Petitioner appealed, again arguing in detail that her extensive expert testimony on causation plainly met the admissibility requirements of the Federal Rules of Evidence, and that binding her to the *Richardson* holding violated the Rules and was unconstitutional. The case was held pending the decision in *Ealy*, and thereafter Merrell moved for summary affirmance.

In a one-page *per curiam* order announced on August 31, 1990, a third, entirely separate panel of the Court of Appeals granted that motion, "substantially for the reasons stated by the district court in its memorandum opinion filed June 30, 1989," and cited both *Richardson* and *Ealy*. (A1-A2). A petition for rehearing and for rehearing *en banc* was filed, emphasizing the unconstitutionality of dismissing the case on this record and urging the Court of Appeals to reconsider its interpretation of Rule 703 and the admissibility of Bendectin evidence in light of the Third Circuit's recent opinion explicitly rejecting the approach of *Richardson* and *Ealy*, in *DeLuca, supra*, 911 F.2d at 950. The petitions were denied on November 7, 1990. (A11-A12).

REASONS FOR GRANTING THE WRIT

I. The decision below flouts the plain statutory language and purpose of Fed. R. Evid. 703, and reveals the need for this Court to resolve the long-standing circuit conflict over Rule 703

The Court of Appeals below, as well as the First Circuit, has interpreted Rule 703 of the Federal Rules of Evidence to give lower federal courts broad authority to decide ultimate issues of scientific fact, by weighing competing expert testimony in the context of making admissibility decisions. Nothing could be further from the clear language and purpose of the Rule, as the Third Circuit has recently summarized in its latest Bendectin case, expressly rejecting the First Circuit's *Lynch* decision and the decisions of the court below in *Richardson* and *Ealy*, and explaining that under Rule 703 the weight and relative persuasiveness of an expert's conclusions are irrelevant. *See DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 952-54 (3d Cir. 1990). The plenary atten-

tion of this Court is warranted both to correct this egregious construction of Rule 703 and to resolve the more general conflict in the circuits over the meaning of Rule 703, which has resulted from the lower courts' failure to heed this Court's instructions for construing the Federal Rules of Evidence.

Unlike the Federal Rules of Civil Procedure and other rules governing the federal courts, the Federal Rules of Evidence are purely creatures of statute. Concerned about the drafting and promulgation of the Rules by the Judiciary, Congress took over the process, made a variety of revisions in the draft, and enacted the rules as a statute. Accordingly, as this Court has unanimously emphasized, "[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' in order to construe their provisions." *Beech Aircraft Corp.* v. *Rainey*, 109 S. Ct. 439, 446 (1988) (citation omitted).[8] The starting point, of course, is the language of the Rules themselves. *Ibid.*; *see also Pennsylvania Dep't of Public Welfare* v. *Davenport*, 110 S. Ct. 2126, 2130 (1990). Moreover, "in all cases of statutory construction, [a court's] task is to interpret the words of . . . statutes in light of the purposes Congress sought to serve," as revealed in the legislative history. *Chapman* v. *Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979).

In enacting the Federal Rules of Evidence, Congress made a fundamental policy choice in its treatment of expert testimony — a policy choice that the court below utterly ignored and overrode, and one that bears heavily on the proper interpretation of Rule 703. Congress embraced deliberately receptive standards for admissibility of expert testimony, making a decision to allow the testimony of any knowledgeable expert

[8] This Court has of course consistently used this traditional approach in its decisions interpreting the Federal Rules of Evidence, rejecting policy-based arguments in construing the Rules. *See generally* Jonakait, *The Supreme Court, Plain Meaning, and the Changed Rules of Evidence*, 68 Tex. L. Rev. 745 (1990).

having specialized information that might assist a jury — and to have the relative weight of testimony thrashed out in the adversary process before the jury.

In doing so, Congress displaced the restrictive, distrustful approach to expert testimony developed over decades by the Federal Judiciary through a common-law approach. Under these rules, for example, an expert was often forced to testify through use of hypothetical questions, thereby limiting the bases of his or her testimony to otherwise admissible evidence; usually an expert could not opine on an "ultimate issue" for fear of invading the province of the jury; and notably under the rule of *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), courts also insisted that expert testimony be based on a methodology enjoying "general acceptance in the particular field in which it belongs," *id.* 1014, thus incorporating a method of peer review for underlying scientific theories.

Such common-law restrictions endured decades of criticism from courts and commentators alike.[9] As Judge Weinstein has noted, their approach "in practice was often stilted, awkward and unduly restrictive." Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 476 (1986). "As technology advanced and expert testimony became more important in the resolution of increasingly complex litigation, unnecessary impediments became unacceptable," and in particular, "it became clear that the *Frye* rule might block the introduction of important and useful testimony." *Id.* at 476-77.

Passage of the Federal Rules of Evidence revolutionized expert testimony. "With little discussion, Congress adopted the opinion rules in nearly the same form as the advisory com-

[9] "Wigmore, McCormick, and other eminent commentators . . . complained for decades about common-law restrictions on opinion evidence that deprived triers of fact of valuable information needed for sounder adjudications." Berger, *United States* v. *Scop: The Common Law Approach to an Expert's Opinion About a Witness's Credibility Still Does Not Work*, 55 Brooklyn L. Rev. 559, 559 (1989).

mittee proposed," which "is perhaps understandable since the rules reflect an enlightened, academic view of opinion testimony that dates back some fifty years." Pratt, *A Judicial Perspective on Opinion Evidence Under the Federal Rules*, 39 Wash. & Lee L. Rev. 313, 314 & n.5 (1982) (citing authorities). The scheme "rel[ies] heavily on the adversary system," and trusts the ability of counsel to present such testimony and of juries to evaluate it. *Id.* at 313. The goal "[t]hat evidence scholars had long been seeking ha[s] now come to pass." Weinstein, *supra*, at 477.

The central expert testimony provision is of course Rule 702; Rule 703 plays a relatively minor role. Under Rule 702, a broad range of persons may qualify as "experts," by virtue of "knowledge, skill, experience, training, or education". As to substance, testimony is permitted as long as "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue."

Rule 702 therefore greatly expands the admissibility of expert testimony, and under it "[a]ny relevant conclusions supported by a qualified expert witness should be received." E. Cleary, *McCormick on Evidence* § 203, at 608 (3d ed. 1984). As the Third Circuit has emphasized, the policy judgment reflected in the Rules "embod[ies] a strong and undeniable preference for admitting any evidence having *some* potential for assisting the trier of fact and for dealing with the risk of error through the adversary process." *DeLuca*, 911 F.2d at 956 (citing *Barefoot* v. *Estelle*, 463 U.S. 880, 899 & 901 n.7 (1983)) (emphasis added).

Despite the clear policy choice made by Congress, the court below has endeavored to construe Rule 703 to give federal courts *carte blanch* to exclude expert opinion testimony based on its relative weight compared with opposing testimony. This view, however, simply flouts the plain language of Rule 703, which makes obvious that the function of the Rule is to expand

available expert testimony *beyond* Rule 702 and streamline trials, by allowing experts to function as they do in everyday work, drawing on their supply of background knowledge in a given field as well as relevant literature, even if this information is inadmissible in evidence.

The text of Rule 703 could not be clearer: as long as the "facts or data" on which an expert bases his or her opinion are "of a type reasonably relied upon by experts *in the particular field* in forming opinions or inferences upon the subject," there is no need for the facts or data to be admissible into evidence (emphasis added). As the Advisory Committee Note to Rule 703 explains, this aspect of "the rule is designed to *broaden* the basis for expert opinions beyond that current in many jurisdictions and to bring the *judicial practice* into line with the *practice of the experts* themselves when not in court" (emphasis added). Notably, the words "in the particular field" were added to Rule 703 in the later stages of drafting in recognition of the fact that the types of data relied on by experts vary among fields.[10]

The whole point of the Rule is thus to modify courtroom procedures to accommodate the customary practice of experts — not to give courts a tool for excluding an expert's conclusions based on a court's perception, in light of the court's own subjective view of the persuasiveness of the underlying data, that is not "reasonable" for the expert to express a given view. The court below, however, totally misapplied Rule 703 by barring *teratologists* from basing opinions in part on

[10]The 1969 version lacked the words "in the particular field." Proposed Rules of Evidence, 46 F.R.D. 161, 315 (1969). The phrase was added on the suggestion of a bar group. American College of Trial Lawyers, *Report of the Comm. to Study the Proposed Rules of Evidence* (1970) ("In Rule [703], concerning expert opinion testimony, it would be desirable in dispensing with facts or data supporting such an opinion to require that the underlying facts or data be of a type reasonably relied upon by an expert versed in the particular field, rather than by experts generally.").

epidemiological evidence not meeting strict tests of "statistical significance" even though they do so in their common practice, merely because experts in *another* field, that of epidemiology, do not do so in *their* common practice.

The Court of Appeals below has never defended its reading of Rule 703 against the analysis of the Third Circuit in the most widely noted case on the issue, *In Re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238 (3rd Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574 (1986). There, the District Court refused to admit into evidence expert antitrust reports or live opinions concerning them, despite uncontradicted affidavits establishing that the data in them were reasonably relied upon by experts in the relevant fields. The District Court proceeded on the policy assumption that, under Rule 703, "given the potential for open-ended receipt into evidence of testimony based upon information of questionable reliability, it is plain that some limitation on the types of information upon which an expert may rely is essential," and that "the judge must be the ultimate arbiter of the reliability of materials upon which an expert witness bases his opinion." *Zenith Radio Corp.* v. *Matsushita Elec. Indus. Co.*, 505 F. Supp. 1313, 1323, 1326 (E.D. Pa. 1980).

The Third Circuit disagreed. It found that "the trial judge misapplied Rule 703 in concluding that he, not the experts in the field, was the source of information about reasonable reliance," 723 F.2d at 280. In a thorough review of the language and history of the provision, the Court of Appeals made amply clear that, where there is a dispute under Rule 703, a trial court must determine the issue *on the trial record before it*, and "[t]he proper inquiry is not what the *court* deems reliable, but what experts in the relevant discipline deem it to be. . . . [T]he district court must make a *factual* inquiry and finding as to *what data experts in the field find reliable*." *Id.* at 276-77

(emphasis added). It explained that the roots of Rule 703 run too deep to allow room for policy adjustments by the courts:

> The indice of reliability under Rule 703 is the fact that experts in the field in question rely on the type of data in forming their opinions. . . . It was this view which the drafters incorporated in Rule 703. They did so over significant opposition. What the trial court did in effect was to reject the decision of the Judicial Conference, the Supreme Court, and Congress and adhere to an unusually restrictive view as to the basis on which an expert's opinion may be laid.

Id. at 277 (citation omitted). Instead, the Court of Appeals encouraged vigorous cross-examination of experts, noting that "the factfinder can be expected to determine the appropriate weight to be given to the testimony." *Id.* at 277-78.

Nor did the Court of Appeals below, in granting summary affirmance in this case, take any account of the Third Circuit's specific Rule 703 opinion in a Bendectin case, *DeLuca*, which explained the illegitimacy of *Richardson, Ealy* and *Lynch*. The *DeLuca* trial court had relied on *Richardson* to rule the plaintiffs' causation evidence inadmissible based on Merrell's recitation of "the great weight of scientific opinion in its favor" as revealed in the few cases in other courts in which Merrell had won summary judgment. 911 F.2d at 944. The trial court excluded the testimony "despite the fact that most of the data relied upon by [the plaintiffs' expert] was data from peer reviewed articles in medical journals" relied upon by Merrell's own expert. *Ibid.*

Reaffirming its landmark *Japanese Antitrust* decision, see *id.* at 952-53 — and illustrating and opining on the sharp conflict among the circuits over whether whole categories of "mass toxic tort" cases can be dismissed based on the mere

absence of "statistically significant" studies — in *DeLuca*, the Third Circuit rejected *Richardson's* and *Ealy's* focus on the *weight* of expert testimony, holding it legally irrelevant to the inquiry mandated by Rule 703:

> [W]e do not view the absence of statistically significant findings or the great weight of contrary opinion as being relevant to the Rule 703 question posed here. *Rule 703 is satisfied once there is a showing that an expert's testimony is based on the type of data a reasonable expert in the field would use* in rendering an opinion on the subject at issue; it does not address the reliability or general acceptance of an expert's methodology.

Id. at 953 (emphasis added). Although the Third Circuit shared *Richardson's* concern about potential abuses "whenever an expert is permitted to testify to an opinion that is based upon reasoning and data that have not been subjected to the review of professional colleagues," it held that "we may not manipulate our interpretation of the Federal Rules of Evidence to exclude expert testimony" nor "impose special burdens of proof on Bendectin plaintiffs . . . ." *Id.* at 952.

Despite the Third Circuit's clear guidance on the meaning of Rule 703, the Court of Appeals below and the *Lynch* court are not the first courts of appeals to misinterpret Rule 703. Although the Third Circuit has been followed by the Fourth,[11] the Sixth,[12] the Seventh,[13] and the Eighth,[14] several other cir-

[11] *Clinchfield Railroad Co.* v. *Lynch*, 784 F.2d 545, 554 (4th Cir. 1986).

[12] *AU Rustproofing Center, Inc.* v. *Gulf Oil Corp.*, 755 F.2d 1231, 1238 (6th Cir. 1985); *Mannino* v. *International Mfg. Co.*, 650 F.2d 846, 851-53 (6th Cir. 1981).

[13] *United States* v. *Bramlet*, 820 F.2d 851, 856 (7th Cir.), *cert. denied*, 484 U.S. 861 (1987); *United States* v. *Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987).

[14] *Hurst* v. *United States*, 882 F.2d 306, 311 (8th Cir. 1989); *Cashman* v. *Allied Products Corp.*, 761 F.2d 1250, 1255 (1985).

cuits have followed the lead of the District Court in the *Japanese Antitrust* case in second-guessing the reasonableness of the types of data on which experts in fact rely: namely, the Second Circuit,[15] a number of decisions in the Fifth Circuit,[16] and at least one decision in the Tenth Circuit.[17]

There is thus a clear, persistent and important conflict in the circuits over the construction of Rule 703 — a rule relevant to virtually every federal trial involving expert testimony. This split over the meaning of Rule 703 cannot be allowed to fester any longer. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence intended to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." S. Rep. No. 93-1277, 93rd Cong., 2d Sess. (1974), at [1974] U.S. Code Cong. & Ad. News 7054. That legislative aim plainly cannot be maintained unless this Court resolves persistent circuit conflicts over rules that are integral to large numbers of trials conducted each day throughout the Nation.

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[15] *United States* v. *Daly*, 842 F.2d 1380, 1387 (2d Cir.), *cert. denied*, 109 S.Ct. 66 (1988); *Shatkin* v. *McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984) (holding that District Court had "the discretionary right under Fed.R.Evid. 703 to determine whether the expert acted reasonably in making assumptions of fact upon which he would base his testimony").

[16] *E.g.*, *Washington* v. *Armstrong World Indus.*, 839 F.2d 1121, 1123 (5th Cir. 1988), and *Viterbo* v. *Dow Chemical Company*, 826 F.2d 420, 422 (5th Cir. 1987) (allowing independent scrutiny of reliability). The Fifth Circuit seems very much in conflict with itself on this issue. *Compare Christopherson* v. *Allied-Signal Corp.*, 902 F.2d 362, 364 (5th Cir. 1990), and *Peteet* v. *Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir. 1989) (appearing to apply more liberal standard), *cert. denied*, 110 S.Ct. 328.

[17] *Head* v. *Lithonia Corp.*, 881 F.2d 941, 943-44 (10th Cir. 1989). This may be the minority view in the circuit. *Compare Wilson* v. *Merrell Dow Pharmaceuticals*, 893 F.2d 1149, 1153-55 (10th Cir. 1990) and *Marsee* v. *United States Tobacco Co.*, 866 F.2d 319, 323 (10th Cir. 1989) (both taking more liberal approach).

II. The decision below rests on common-law evidence rulemaking that is incompatible with the Federal Rules of Evidence

Even if the construction of *Rule 703* reached by the Court of Appeals below had any merit and could be applied in an individual case, the Federal Rules of Evidence as a whole plainly bar the courts of appeals from ordering trial judges to exclude, as a "matter of law," particular expert conclusions in entire categories of *future* cases.

Rule 401 defines "relevant evidence" as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." (Emphasis added.) Rule 402 states the broad policy of the Federal Rules of Evidence — expansive admissibility — *and* itemizes the only grounds for excluding evidence:

> All relevant evidence is admissible, *except* as otherwise provided [1] by the Constitution of the United States, [2] by Act of Congress, [3] by these rules or [4] by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Emphasis and brackets added). Finally, Rule 104(a) requires that admissibility decisions under Rule 402 be made by the *trial* court *on the record* in the *individual* case; this allocation of judicial authority clearly applies to Rule 703 determinations.[18]

The pre-1975 freedom of the federal appellate courts to create *ad hoc* common-law evidence rules is therefore gone,

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[18] The court below ignored hornbook law that "[t]he question whether reliance by an expert is reasonable as required by FRE 703 involves a factual judgment to be made by the trial judge pursuant to Rule 104(a)." 3 D. Louisell & C. Mueller, *Federal Evidence* § 389, at 418 (West Supp. 1988) (citations omitted).

for Rule 402 does not authorize federal courts to impose new exceptions on admissibility. In exercise of its undoubted power to supplant judge-made procedure,[19] and to secure nationwide uniformity in evidence law, *see supra* p. 25, Congress has thus stripped the federal courts of the authority to promulgate the type of customized admissibility limits imposed by the court below.[20] The only exception to uniformity is found in Rule 501, which permits common-law development of privilege doctrine "in the light of reason and experience" — indicating that Congress's failure to authorize the courts of appeals to dictate exclusion "as a matter of law" was a deliberate one.

III. The decision below is unconstitutional because federal courts are barred from employing the Rules of Evidence to pronounce conclusions about ultimate scientific fact that bind absent third parties on state law issues.

Regardless of the authority under the Federal Rules of Evidence for the order of the court below, the D.C. Circuit's approach violates three key constitutional guarantees in federal court cases involving state tort law.

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[19] Even the power of *this* Court "to prescribe rules of procedure and evidence for the federal courts exists only in the absence of a relevant Act of Congress," *Palermo* v. *United States*, 360 U.S. 343, 353 n.11 (1959). Under the Necessary and Proper Clause, "Congress has undoubted power to regulate the practice and procedure of federal courts." *Sibbach* v. *Wilson & Co.*, 312 U.S. 1, 9 (1941).

[20] *See* Imwinkelried, *The Meaning of Probative Value and Prejudice in Federal Rule of Evidence 403: Can Rule 403 Be Used to Resurrect the Common Law of Evidence?*, 41 Vand. L. Rev. 879, 881-83 (1988); Weissenberger, *The Former Testimony Hearsay Exception: A Study in Rulemaking, Judicial Revisionism, and the Separation of Powers*, 67 N. Car. L. Rev. 293, 33134 (1989). Quite apart from Rule 402, in the sphere of federal judge-made law this Court adopts a *presumption* that relevant legislation displaces past judge-made rules. Congress displaces federal judge-made law simply by comprehensively addressing a particular matter — here, admissibility of expert testimony — and *failing* to preserve judge-made law. *Milwaukee* v. *Illinois*, 451 U.S. 304, 315 (1981) (citation omitted).

(1) Under the Seventh Amendment both parties are entitled to have a jury resolve disputed issues of historical and scientific fact. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge." *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). The D.C. Circuit's creative use of Rule 703 to work a takeover of these essential functions plainly violates the Seventh Amendment, for it has no conceivable analog to procedural law circa 1791. *Parklane Hosiery Co.* v. *Shore*, 439 U.S. 322, 336-37 (1979). Yet the whole point of the Seventh Amendment is to check the power of the federal courts by placing cases in the hands of people other than the sovereign's judges, no matter how inefficient this can be. See id. at 337-56 (Rehnquist, J., dissenting); *see also Granfinanciera, S.A.* v. *Nordberg*, 109 S. Ct. 2782, 2813 (1989) (White, J., dissenting) ("The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge").

(2) Both parties, of course, are entitled to be represented at a hearing, to have their day in court during which they can present probative evidence, and to have decision of factual issues based on *their* record — regardless of how many other litigants have raised similar issues and how much more efficient it might be to bind them to the results of past cases. *E.g.*, *Martin* v. *Wilks*, 109 S. Ct. 2180, 2184-88 (1989); *Blonder-Tongue Laboratories, Inc.* v. *University of Illinois Foundation*, 402 U.S. 313, 329 (1971). Yet plaintiffs in the D.C. Circuit are told simply that the conclusions that *their* experts pronounce have already been considered through the proxy of *other* litigants and experts, in an earlier case, and were rejected as outweighed by supposedly contradictory evidence — and that these later plaintiffs are bound by this earlier factual assessment. Petitioner litigated for a decade, and survived two summary judgment motions, only to be told that her claims had al-

ready been heard and rejected. In effect the D.C. Circuit imposed a surprise, mandatory class action to decide whether Bendectin is a teratogen, and bound all future plaintiffs without any of the procedural protections that would be afforded under an actual class action. *Cf. Phillips Petroleum Co.* v. *Shutts*, 472 U.S. 797, 811-12 (1985).

(3) The relevant Article III courts must limit themselves to adjudicating "cases or controversies" and must not disregard the state substantive law that controls the case. In Bendectin cases the D.C. Circuit has functioned instead like "a sort of junior-varsity Congress," *Mistretta* v. *United States*, 109 S. Ct. 647, 683 (1988) (Scalia, J., dissenting), enacting its own legislative fact findings and conclusive presumptions for the District of Columbia, evading the constraints on such activity in Fed. R. Civ. P. 201. Mistakenly relegating federalism concerns to the status of "*Erie*" problems that can be avoided under the authorization of the Rules Enabling Act, *see supra* notes 5, 6, & 7, the D.C. Circuit has manipulated a self-contained federal statute — the Federal Rules of Evidence — to completely displace District of Columbia tort law, without any clear statement from Congress that this is permissible.

Acknowledgement of these three elementary principles in the context of "mass tort" cases has varied. Inspired by the D.C. Circuit's *Richardson* holding, a panel of the Fifth Circuit violated all three in *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990). Professing a need to confront the "special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker" in "mass tort" cases, the Court of Appeals found it important to prevent juries from splitting "both ways" on common factual issues that "may be just a matter of opinion," in order to avoid "a sub-optimal amount of new drug development," and consequently it proclaimed

that judgment n.o.v. must be entered against all future Bendectin plaintiffs lacking "statistically significant" causation evidence. *Id.* 309-10, 315. While expressing sympathy with such policy concerns, the Third Circuit in *DeLuca* adhered to all three principles and rejected *Brock*'s and the D.C. Circuit's customized approach to Bendectin cases. 991 F.2d at 950-52.

Judge Patrick Higgenbotham, writing for the Fifth Circuit, honored these principles in the context of the far more burdensome asbestos litigation, by rejecting a District Court's plea that a quasi-administrative scheme, which would have denied defendants Seventh Amendment and due process rights in thousands of cases and displaced state tort law policy choices, was necessary to resolving these cases. *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990). Suggesting that the representative branches be consulted, he apologized that "[t]he Judicial Branch can offer the trial of lawsuits. It has no power or competence to do more." *Id.* at 712.

The lower federal courts would benefit from reaffirmation of these central principles in the "mass tort" context. At minimum, the exercise of this Court's supervisory power is warranted to halt the D.C. Circuit's aberrant use of the Federal Rules of Evidence to deny the statutory and constitutional rights of plaintiffs, and to settle the disagreement among the courts of appeals on these basic questions.

CONCLUSION

For the reasons stated above, a writ of certiorari should be granted.

Respectfully submitted,

KENNETH J. CHESEBRO
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February 5, 1991

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APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 89-7167 September Term, 1989

C.A. No. 80-01258

Filed Aug. 31 1990

ANNE ELISABETH KOLLER,
APPELLANT

v.

RICHARDSON-MERRELL, INC.

BEFORE: Ruth B. Ginsburg, Buckley and Sentelle, Circuit Judges

ORDER

Upon consideration of appellee's motion for summary affirmance, the response thereto, and the reply, and appellant's motion to strike, it is

ORDERED that the motion to strike be denied. It is

FURTHER ORDERED that the motion for summary affirmance be granted substantially for the reasons stated by the district court in its memorandum opinion filed June 30, 1989. *See also Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990), *petition for cert. filed*, 59 U.S.L.W. 3095 (U.S. Aug. 1, 1990) (No. 90-225); *Richardson v. Richardson-Merrell, Inc.*, 856 F.2d 823 (D.C. Cir. 1988), *cert. denied*,

110 S. Ct. 218 (1989). The merits of the parties' positions are so clear as to justify summary action. *See Taxpayers Watchdog, Inc. v. Stanley*, 819 F.2d 294, 297 (D.C. Cir. 1987) (per curiam); *Walker v. Washington*, 627 F.2d 541, 545 (D.C. Cir.) (per curiam), *cert. denied*, 449 U.S. 994 (1980).

The Clerk is directed to withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing. *See* D.C. Cir. Rule 15.

Per Curiam

APPENDIX B

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

Civil No. 80-1258

VS.

RICHARDSON-MERRELL, INC.
DEFENDANT.

Filed June 30, 1989

MEMORANDUM OPINION

Bendectin, a prescription drug manufactured by defendant, Richardson-Merrell Inc.,[1] to ease the nausea and vomiting often associated with pregnancy, has been the subject of numerous lawsuits. In this case, plaintiffs, Anne Elisabeth Koller and her parents, John Lamont and Cynthia Anne Koller, filed a complaint alleging that the ingestion of Bendectin by the mother during her pregnancy caused the minor plaintiff to be born with severe birth defects. Following the completion of discovery but before trial, this action was stayed pending a decision by the United States Court of Appeals for the District of Columbia Circuit in a case involving an identical question of law. That decision was rendered on September 27, 1988, and styled *Richardson v. Richardson-Merrell*, 857 F.2d 823 (D.C. Cir. 1988). The Court will now address the effect of the *Richardson* decision on the instant action.

[1] Richardson-Merrell, Inc. is now doing business as Merrell Dow Pharmaceuticals, Inc.

BACKGROUND

This case, filed in 1980, was finally scheduled for trial after the *Richardson* case. Aware of the significance of the holding in that case, a stay was granted on the motion of defendant pending the decision of the Court of Appeals.

On October 14, 1988, following the decision in *Richardson*, defendant moved to have the stay lifted and for an order to have plaintiffs show cause why this case should proceed in light of the holding in that case. This motion was granted, and the plaintiffs were directed to identify specific, admissible, expert evidence of a causal relationship between Bendectin and limb defects which would meet the standards announced in the *Richardson* decision.

Plaintiffs responded to the Order to Show Cause, arguing, in the first instance, that the *Richardson* case is not controlling over this action, and in the alternative, that the Court should permit a jury to consider the evidence adduced by plaintiffs to prove causation. Defendant argues that the *Richardson* decision is dispositive; that all of the evidence proffered by plaintiffs to demonstrate a causal link between Bendectin and Anne's limb defects has been declared inadmissible by the Court of Appeals in the *Richardson* case.

DISCUSSION

Before deciding whether plaintiffs may proceed to trial on the evidence proffered in their 26(b)(4) statements filed on December 15, 1982, an analysis of the *Richardson* decision is warranted. The jury in that case, after hearing the testimony of experts presented by both plaintiffs and defendants, found that Bendectin is a human teratogen and capable of causing birth defects in humans. It further concluded that Bendectin was the proximate cause of the birth defects experienced by the

minor plaintiff in *Richardson*. The trial court granted the motion of defendant for judgment *non obstante veredicto* and found that a reasonable jury could not conclude, based upon the evidence presented by plaintiffs at trial, that a causal connection between Bendectin and limb defects existed. In the alternative, the court granted the motion of defendants for a new trial.

The Court of Appeals affirmed the decision of the trial judge. It concluded that while the issue before it is scientific in nature and "expert witnesses are indispensable," the Court need not "accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify." *Richardson, supra,* at 829. The Court found that in order for evidence to be presented to a jury it must be "a type reasonably relied upon by experts in the particular field . . ." and should not be given to a jury if it "only 'provides a mere possibility yet not a probability of proof.' " *Id.* (quoting *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1093-94 (D. Md. 1986), *aff'd without opinion sub nom. Wheelahan v. G. D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987).

The Court then analyzed the various types of evidence presented by the plaintiffs' primary expert witness, Dr. Alan K. Done. The court's purpose in so doing was to determine if there is a scientifically sound foundation to support his testimony that there is a causal connection between ingestion of Bendectin during pregnancy and birth defects.

Dr. Done relied upon four different types of studies to reach his conclusion: 1) chemical structure activity analysis; 2) *in vivo* studies; 3) *in vitro* studies; and 4) recalculated data from epidemiological studies. The Court analyzed each one to determine their scientific reliability.

Beginning with the chemical structure studies, the Court of Appeals noted that the investigation by Dr. Done of Bendectin's chemical structure revealed similarities between the anti-

histamine component of the drug and other antihistamines which have been found to cause birth defects in animals. The Court found, however, that the effect of these antihistamines on humans has not been determined. Moreover, chemical structure analysis, as a scientific methodology, was found to provide little proof of causation. "As Dr. Done acknowledged, the purposes of analyzing chemical structures is to indicate what other directions a study of a substance should take; in other words, chemical structure activity analysis 'gives you a clue,' or 'raises at least a flag to you indicating that this is a drug that you ought to and must study for teratologic effect . . .'" *Id.* at 830 (quoting the Trial Transcript at 798). From this conclusion, the Court determined that the chemical structure studies relied upon by Dr. Done to support his testimony were not valuable.

Turning to the *in vitro* (animal) studies used by Dr. Done, the Court of Appeals found that the doctor's own testimony supported a conclusion that while animal studies are useful in determining if further tests should be performed, they, like chemical structures studies, "serve merely to raise a suspicion regarding the effect of Bendectin on humans . . ." *Id.* Consequently, this evidence cannot, in a court of law, serve as a foundation for the doctor's expert opinion.

A similar conclusion was reached with respect to *in vitro* (test tube) studies. Again, the Court of Appeals concluded that "the value of such an examination as a predictor of human teratogenicity is extremely meager . . ." *Id.* Having assessed the value of these three types of scientific research and finding them insufficient to support Dr. Done's testimony, the Court determined that "[s]tudies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence." *Id.*

The Court of Appeals then turned to an assessment of the epidemiological studies presented at trial. The defendant relied entirely upon these types of studies; all of which concluded that there was no statistically significant correlation between the use of Bendectin and the incidence of birth defects. Dr. Done conceded that no published work has found this causal link, but relying upon his own recalculations of the epidemiological data available, Dr. Done concluded that there was a statistically relevant correlation. The court expressed skepticism about the value of Dr. Done's recalculations, noting that they were never published nor submitted for peer review while those offered by defendant had been distributed and discussed in the scientific community.

Having thus rejected all of the scientific testimony offered to support the expert testimony of Dr. Done, the Court found that, as a matter of law, the expert testimony presented by plaintiffs at trial could not support a finding of causation. The Court concluded that plaintiffs failed to meet their burden of proof. "[T]he law cannot tolerate a presumption of teratogenicity . . . when [it] becomes an issue in a judicial tribunal." *Id.* at 831. Accordingly, the Court of Appeals affirmed the decision of the District Court and found in favor of defendants.

Plaintiffs maintain that this Court is not bound by the decision in *Richardson* as the doctrine of collateral estoppel does not apply. While plaintiffs correctly argue that the *Richardson* decision does not automatically dispose of the instant action, the precedential value of a decision which is factually similar and is rendered by the Court of Appeals for this jurisdiction, cannot be ignored. *See AFL-CIO v. Marshall,* 617 F.2d 636 (D.C. Cir. 1979); *Department of Energy v. Westland,* 565 F.2d 685 (Cust. & Pat. App. 1977). It is axiomatic that a district court is to follow the law of its own circuit, unless the cases are factually distinguishable.

This Circuit has found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, *in vivo*, *in vitro* studies, or reformulated epidemiological data, is not admissible. Consequently, expert testimony in a Bendectin case cannot be presented to a jury unless it is supported by some other type of scientific evidence. The burden on plaintiffs is to demonstrate that they will provide the jury with expert testimony which relies upon studies other than those disapproved by the Court of Appeals.

Plaintiffs have not met this burden. The majority of the brief submitted by plaintiffs in response to the Order to Show Cause is devoted to an attempt to refute the *Richardson* decision. They attack the conclusion of the Court of Appeals that only the epidemiological studies provided by the defendant are valid as evidence and argue that the *in vivo*, *in vitro*, and restructured epidemiologic studies offered in this case are sufficient to support expert testimony. At least, they maintain, the evidence should be presented to a jury. Plaintiffs refer the Court to cases where this evidence was found to be admissible at trial; however, not one of these cases is controlling.

Given that the evidentiary standards articulated in *Richardson* are controlling here, the majority of plaintiffs' brief is irrelevant. Indeed, nowhere in their papers do the plaintiffs identify any evidence demonstrating causation which would be acceptable under the principles of *Richardson*.

Pursuant to the decision in *Richardson*, it was incumbent upon plaintiffs in this action to demonstrate that they will rely upon scientific evidence other than that which was rejected by the Court of Appeals. Plaintiffs have failed to do so. Instead, they have sought to have this Court decline to follow the decision of the Court of Appeals and find that the scientific evidence proffered by the plaintiffs is reasonable and may be presented to a jury. This the Court refuses to do. The law of this Circuit is that announced in *Richardson*: the issue of causa-

tion shall not be presented to a jury unless the plaintiffs offer scientific evidence other than that which has heretofore been proffered.

CONCLUSION

Accordingly, the Court finds that plaintiffs have failed to meet their burden of proving causation such that the issue may be presented to a trier-of-fact. Judgment in favor of defendant should, therefore, be entered. An Order consistent with this Memorandum Opinion will issue.

DATED: June 30, 1989

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

Filed June 30, 1989

ORDER AND JUDGMENT

Upon consideration of the record in this case, the memoranda of the parties, and the accompanying Memorandum Opinion, it is this 30th day of June, 1989,

ORDERED that judgment be, and hereby is, entered in favor of defendant; and it is further

ORDERED that the complaint herein be, and hereby is, dismissed.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

APPENDIX C

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 89-7167 September Term, 1990

U.S.D.C. Civ. No. 80-1258

Filed Nov. 7 1990

ANN ELISABETH KOLLER,
APPELLANT,

v.

RICHARDSON-MERRELL, INC.

BEFORE: Ruth B. Ginsburg, Buckley and Sentelle,
Circuit Judges

ORDER

Upon consideration of appellant's Petition for Rehearing, filed October 1, 1990, it is

Ordered, by the Court, that the petition is denied.

Per Curiam

FOR THE COURT:
CONSTANCE L. DUPRE, CLERK

BY: /s/ _____
Robert A. Bonner
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 89-7167

September Term, 1990
USDC Civ. No. 80-1258
Filed Nov. 7 1990

ANN ELISABETH KOLLER,
APPELLANT,

v.

RICHARDSON-MERRELL, INC.

BEFORE: Wald, Chief Judge; Mikva, Edwards, Ruth B. Ginsburg, Silberman, Buckley, Williams, D. H. Ginsburg, Sentelle, Thomas, Henderson and Randolph, Circuit Judges

ORDER

Appellant's Suggestion for Rehearing *En Banc* has been circulated to the full Court. No member of the Court requested the taking of a vote thereon. Upon consideration of the foregoing it is

Ordered, by the Court, *en banc*, that the suggestion is denied.

Per Curiam

FOR THE COURT:
CONSTANCE L. DUPRE, CLERK

BY: /s/ _____
Robert A. Bonner
Deputy Clerk

Chief Judge Wald did not participate in this matter.

APPENDIX D

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA

Filed Jan. 25 1983

ANNE ELISABETH KOLLER, *et al.*,
PLAINTIFFS,

v. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

MEMORANDUM OPINION

This matter is before the Court on defendant's motion for summary judgment on the issue of whether Bendectin caused the birth defects of Anne Koller. Defendant contends that plaintiffs' argument that Bendectin is a teratogen that causes limb reductions rests on such speculative evidence and opinions that defendant is entitled to summary judgment. Although defendant does isolate what it considers as weaknesses in plaintiffs' case that may have a significant bearing on whether a directed verdict eventually should be granted, defendants have failed to demonstrate at this point in the proceedings that a genuine issue of material fact does not remain concerning whether Bendectin caused Anne Koller's birth defects. Accordingly, defendant's motion for summary judgment on the issue of causation will be denied.

Defendant makes three arguments to support its contention that plaintiffs' case is nothing more than speculation. First, defendant maintains that plaintiffs are unable to present an

accepted mechanism to explain how Bendectin causes limb reductions. Second, defendant suggests that even though plaintiff may be able to rule out all other known causes of birth defects, Bendectin did not necessarily cause Anne Koller's birth defects because the cause of a majority of all birth defects is unknown. Third, defendant claims that Bendectin did not necessarily cause Anne Koller's birth defects because limb reductions have occurred before Bendectin ever was developed and in countries where Bendectin has never been distributed. While all of defendants' arguments suggest obstacles that plaintiffs will have to confront in presenting their case, none of these arguments is sufficiently compelling to justify the granting of defendant's motion for summary judgment.

Defendant's first argument is that it is entitled to summary judgment because plaintiffs can only speculate on the mechanism by which Bendectin causes limb reductions. Defendant points out that many of plaintiffs' experts have offered no explanation for how Bendectin can act as a teratogen and that those experts of plaintiffs that have suggested three separate theories have relied solely on speculation unconfirmed by any scientific experimentation. It is true that defendant may be able to preclude plaintiffs from presenting any theories to explain Bendectin's teratogenicity if those theories cannot be advanced with any experimental foundation. Yet, the inability to provide any technical explanations for how Bendectin actually causes birth defects does not have a fatal impact on plaintiffs' case. The mechanism by which an allegedly injurious product actually carries out its damage is simply not a prima facie element of plaintiffs' case. For example, while a plaintiff may not be able to explain precisely how a product has triggered a disease such as cancer (a disease whose triggering mechanism has so far eluded the best medical minds), a plaintiff still can prevail if it can be shown by a preponderance of the evidence that the product was responsible for the condition. Of course,

plaintiffs' case may appear weaker if they cannot identify the precise manner in which Bendectin allegedly causes birth defects. Nevertheless, providing the mechanism by which Bendectin allegedly triggers birth defects does not appear to be an essential element of plaintiffs' case.

Defendant's remaining two arguments to support summary judgment are so related in nature that they can be analyzed in a similar manner. Both arguments are founded on the proposition that there are so many unknown factors responsible for birth defects that the fact that Ms. Koller allegedly ingested Bendectin and later gave birth to a child that suffered severe birth defects is insufficient to permit the inference that Bendectin causes these birth defects. Specifically, defendant relies on the conclusions of plaintiffs' experts that the causes of a majority of all birth defects are unknown and that children whose mothers never took Bendectin have suffered limb reductions. In essence, defendant suggests that the natural (unexplained) incidence of birth defects is so high that taking Bendectin during the first trimester is an insufficient basis to infer that Bendectin was responsible for the limb reductions that later occurred. Although defendant's arguments do indicate that attempting to demonstrate that any particular product causes birth defects is a formidable task, it fails to eliminate causation as a genuine issue of material fact at this juncture. The Court cannot conclude that the figures upon which defendant's arguments rest, *e.g.*, multiple limb reductions occurring at a rate of 1-100,000 to 1-1,000,000 live births are anything more than guesstimates that may not be presentable with sufficient certainty to constitute admissible evidence. Moreover, the Court rejects the full implications of defendant's arguments that would effectively deprive any plaintiff of reaching the jury where the product at issue was not an *accepted* cause of birth defects or other diseases. Consequently, the fact that birth defects such as those suffered by Anne Koller have been caused

by unexplained factors (which could have included Bendectin in some instances) does not nullify plaintiffs' contention that Bendectin caused the birth defects of Anne Koller.

What defendant's arguments concerning the significant proportion of birth defects with no explained cause have made clear is that plaintiffs must demonstrate that Bendectin actually caused Anne Koller's birth defects. Defendant has strenuously maintained that there is not a shred of evidence to indicate that there is positive relationship between Bendectin and birth defects. While plaintiffs may have difficulty withstanding a motion for a directed verdict, it appears premature to dismiss plaintiffs' case based on the present record.* Admittedly, defendants have identified some problems with plaintiffs' case. For example, even if the drug experience reports prove admissable, defendants may be entitled to a jury instruction that the drug experience reports alone are insufficient to support a finding that Bendectin causes limb reductions. In addition, it is questionable whether plaintiffs will be able to employ any of the epidemiological or animal studies to prove that Bendectin is a teratogen.** Yet, the complexity of the issue of causation combined with the presence of some uncertainty over what plaintiffs' experts will assert requires that the Court permit plaintiffs at least to present their case to the jury.

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* In virtually all of the cases that defendant cites to support the granting of summary judgment on issue of causation, particularly the swine flu cases, the courts had the benefit of plaintiffs' presentation of their evidence before they found that the plaintiffs had failed to demonstrate causation.

** There is concern whether plaintiffs' experts will be permitted to present any conclusions concerning the epidemiological studies that are not based on an accepted level of statistical significance. Another concern is that plaintiffs have cited a plethora of alleged methodological errors in the epidemiological and animal studies. It is unclear whether any of these alleged errors will be admissable unless plaintiffs can provide a sufficient foundation that the correction of these errors would alter the conclusions of the studies.

An Order consistent with this Memorandum Opinion will be entered this date.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

DATE: January 24, 1983

United States District Court

FOR THE DISTRICT OF COLUMBIA

Filed Jan 25, 1983

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

ORDER

Upon consideration of defendant's motion for summary judgment on the issue of causation, plaintiffs' opposition, the accompanying memoranda, and the entire record herein, it is this 24th day of January, 1983,

ORDERED that defendant's motion for summary judgment on the issue of causation be, and hereby is, denied.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

APPENDIX E

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

Filed Sep 26 1986

ORDER

Upon consideration of the motion of the plaintiffs for partial summary judgment, defendant's opposition thereto, the parties respective legal memoranda, and the record herein, and it appearing to the Court that there is no basis in law to collaterally estop defendant from litigating the issue of causation in this action, it is this 26th day of September, 1986,

ORDERED that plaintiffs' motion for partial summary judgment be, and hereby is, denied.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

APPENDIX F

United States District Court

FOR THE DISTRICT OF COLUMBIA

ANNE ELISABETH KOLLER,
et al.,
PLAINTIFFS,

vs. Civil Action No. 80-1258

RICHARDSON-MERRELL, INC.,
DEFENDANT.

Filed Sep 26 1986

ORDER

Upon consideration of the renewed motion of defendant for summary judgment on the issue of causation, plaintiffs' opposition thereto, the parties' respective legal memoranda, together with the affidavits, exhibits, and the entire record herein, and it appearing to the Court that there exists a genuine issue of material fact as to whether Bendectin caused Anne Koller's birth defects, it is this 26th day of September, 1986,

ORDERED that defendant's renewed motion for summary judgment on the issue of causation be, and hereby is, denied.

/s/ _____
NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE